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Docket No.: 102258.346

PATENT/OFFICIAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

David S. GARVEY et al.

Serial No. 09/478,222

Filed: January 5, 2000

For: METHODS FOR TREATING HUMAN IMPOTENCE WITH NITRIC OXIDE DONOR COMPOUNDS

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: Group Art Unit: 1639  
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: Examiner: Bennett M. Celsa

TECH CENTER 1600/2800  
DEC 23 2003

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached form PTO-1449. It is respectfully requested that the documents be expressly considered during the prosecution of this application, and that the documents be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

In accordance with 37 C.F.R. § 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search had been made or that information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item, and Applicant reserves the right to prove that the date of publication is in fact different.

Copies of the documents listed on Form PTO-1449, some of which were cited in the prosecution of the corresponding PCT patent application, are enclosed. A copy of the search

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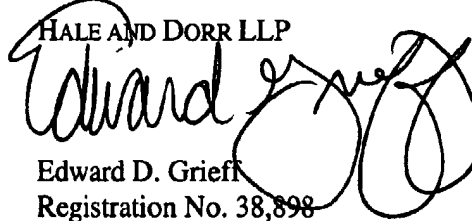
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report for the PCT patent application is also enclosed.

The fee of \$180.00 pursuant to 37 CFR § 1.17(p) is attached. The Commissioner is authorized to charge any deficiency in any fees pursuant to 37 CFR § 1.17 associated with this communication and to credit any excess payment to Deposit Account No. 08-0219.

Respectfully submitted,

HALE AND DORR LLP

  
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Date: December 17, 2003

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SHEET 1 OF 2

<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  (PTO-1449)				ATTY. DOCKET NO. <b>102258.346</b>		SERIAL NO. <b>09/478,222</b>	
				APPLICANT <b>Garvey et al.</b>			
				FILING DATE <b>January 5, 2000</b>		GROUP <b>1639</b>	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE	
	3,331,855	7/18/67	Popelak et al.			6/5/64	
	3,574,212	4/6/71	Hess et al.			2/2/68	
	3,940,387	2/24/76	Saint-Ruf et al.			5/5/72	
	3,997,666	12/14/76	Witte et al.			1/28/75	
	4,060,615	11/29/77	Matier et al.			2/18/76	
	4,959,360	9/25/90	Lafferty et al.			6/6/89	
	5,096,916	3/17/92	Skupin et al.			5/7/90	
	5,236,904	8/17/93	Gerstenberg et al.			9/18/84	
	5,380,758	1/10/95	Stamler et al.			9/14/92	
	5,399,581	3/21/95	Laragh et al.			12/26/90	
	5,403,847	4/4/95	Gluchowski et al.			11/13/92	
	5,447,912	9/5/95	Gerstenberg et al.			8/16/93	
<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	1249261	10/13/71	GB			X	
	1533529	11/29/78	GB			X	
	1548856	7/18/79	GB			X	
	9312068	6/24/93	WO			X	
	9505172	2/23/95	WO			X	
	9507075	3/16/95	WO			X	
	9632118	10/17/98	WO			X	
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	Urech, E. et al. 1950. "2-Aminoalkyl-imidazoline." <i>Helvetica Chimica Acta</i> . pp. 1386-1407.						
	Dewar, G.H. et al. 1983. "Some Potential alpha-adrenoceptor blocking 1, 4-benzodioxanes and 2, 6-dimethoxyphenoxyethylamines." <i>Eur. J. Med. Chem. Chim. Ther.</i> Vol. 18, No. 3, pp. 286-290.						
	Melchiorre, C. et al. 1984. "2-[[[2-(2,6-Dimethoxyphenoxy)ethyl]amino]-methyl]-1,4-benzoxathian: A New Antagonist With High Potency and Selectivity Toward alpha1-Adrenoreceptors." <i>J. Med. Chem.</i> Vol. 27, No. 12, pp. 1535-1536.						
	Welbourn, A.P. et al. 1986. "Alpha-Adrenoceptor Reagents. 4. Resolutions of Some Potent Selective Prejunctional alpha2-adrenoceptor Antagonists." <i>J. Med. Chem.</i> Vol. 29, pp. 2000-2003						
	Mitani, K. et al. 1988. "Novel Phenoxyalkylamine Derivatives. V. Synthesis, alpha-Blocking Activity and Quantitative Structure-Activity Analysis of alpha-(Phenoxyethylamino)propyl-1-alpha-phenylacetone nitrile Derivatives." <i>Chem. Pharm. Bull.</i> Vol. 36, No. 10, pp. 4121-4135.						
	EXAMINER 			DATE CONSIDERED 3/26/04			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

## INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(PTO-1449)

ATTY. DOCKET NO.

**102258.346**

SERIAL NO.

**09/478.222**

**APPLICANT**

Garvey et al.

FILING DATE

**January 5, 2000**

GROUP

1639

**OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

Pigini, M. et al. 1988. "Structure-Activity Relationships in 1, 4-Benzodioxan-Related Compounds. Investigation on the Role of the Dehydrodioxane Ring on alpha(1)-Adrenoreceptor Blocking Activity." *Journal of Medicinal Chemistry*. American Chemical Society, Washington. Vol. 31, No. 12, pp. 2300-2304

Chenard, B.L. et al. October 1, 1991. "Separation of Alpha Adrenergic and N-Methyl-D-Aspartate Antagonist Activity in a Series of Ifenprodil Compounds." *Journal of Medicinal Chemistry*. American Chemical Society, Washington. Vol. 34, No. 10, pp. 3085-3090.

Zorgniotti, A.W. March 1, 1994. "Experience With Buccal Phentolamine Mesylate For Impotence." *International Journal of Impotence Research*. Vol. 6, No. 1, pp. 37-41

Wetzel, J.M. et al. May 12, 1995. "Discovery of Alpha 1A-Adrenergic Receptor Antagonists Based on the L-Type CA2+ Channel Antagonist Niguldipine." *Journal of Medicinal Chemistry*. American Chemical Society, Washington. Vol. 38, No. 10, pp. 1579-1581.

Regunathan, S et al. 1996. "Imidazoline Receptors and Their Endogenous Ligands." *Annual Review of Pharmacology and Toxicology*. Annual Review, Inc. Palo Alto, CA. Vol. 36, pp. 511-544.

Andersson, K.E. 2001. "Pharmacology of Penile Erection." *Pharmacological Reviews*. Vol. 53, No. 3, pp. 417-450.

Andersson, K.E. et al. 2001. "Oral Alpha Adrenoceptor Blockade as a Treatment of Erectile Dysfunction." *World J. Urol.* Vol. 19, pp. 9-13.

Tam, S.W. et al. 2001. "Yohimbine: A Clinical Review." *Pharmacology & Therapeutics*. Vol. 91, pp. 215-243.

June 6, 2002. European Search Report for European Application No. 97904887.3.

**EXAMINER**

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re the Application of: **GARVEY et al**

Application No.: **09/478,222**

Group Art Unit: **1627**

Filed: **January 5, 2000**

Examiner: **B. Celsa**

For: **Nitrosated and Nitrosylated Alpha-Adrenergic Receptor  
Antagonist Compounds, Compositions and Their Uses**

Attorney Docket No.: **102258.346**

Commissioner of Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form. A copy of the documents is submitted herewith.

The pending claims in US Publication No. 2002/0061879 (i.e., US Application No. 10/024,550) are submitted herewith for the Examiner's consideration.

The pending claims in US Publication No. 2003/0158184 (i.e., US Application No. 10/024,040) are submitted herewith for the Examiner's consideration.

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed document is material to patentability or that the listed document is prior art.

This Information Disclosure Statement is being filed after the mailing date of a first office action on the merits, but before a final office action or notice of allowance. Accordingly, the Commissioner is authorized to charge the fee of \$180 to Deposit Account No. 08-0219. The Commissioner is authorized to charge any other necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the application.

Applicants respectfully request that the Examiner return an initialed copy of the PTO-1440 Form with the next communication from the PTO.

Respectfully submitted,

*Edward D. Grief*  
Edward D. Grief  
Registration No. 38,898

Date: January 26, 2004  
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1455 Pennsylvania Avenue, NW  
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Phone: (202) 942-8400

**Complete if Known**

**(Use as many sheets as necessary)**

Sheet 1

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Attorney Docket Number	102258:346
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.**